FDA

MAUDE Adverse Event Report: CERNER CERNER CALCULATOR/DATA PROCESSING MODULE, FOR CLINICAL USE

CERNER CERNER CALCULATOR/DATA PROCESSING MODULE, FOR CLINICAL USE Back to Search Results

Event Type No Answer Provided

Event Description

I am a pharmacist in a (b)(6) hospital. Our facility recently changed to cerner as out healthcare information system for the entire hospital system including physician offices. The system allows providers to order any medication by any route. Since our (b)(6) initiation, we have had instances where depo-medrol has been given iv rather than im, received orders for bisacodyl suppository and restoril capsules all iv push, and bupropion tablets via otic route. There is no system safeguard for route. There is no product selection safeguard. For example, if an order for sodium chloride 50 ml of 0. 9 percent comes to pharmacy for product verification, the system suggests every sodium chloride product (tablets, irrigation, etc) including high concentration 23. 9 percent and will then allow the user to select it, resulting in a dose of 50 ml 23. 9 percent. There is also no dose range checking. It allowed a physician to order motrin 500 mg/kg on an infant with no warning, calculated the dose, and had no safeguard or warning to pharmacy. Alert warnings for duplicate therapy/ allergies have often not alerted providers, but on review of the prescription the system is recording that the pharmacist did indeed override the alert that never actually happened. The system does not provide a way for providers to accurately identify the encounter number (visit number) applicable for a specific date resulting in orders being placed on the wrong visit number. Furthermore, the physician progress note and pharmacist active medication list will show these orders/medications across all encounters, resulting in an inaccurate representation of the active inpatient medication list. (ie: orders for every visit number for that pt are included in active medication list so it appears to providers that the medication is indeed ordered, but since it is not on the correct encounter, it does not show on the inpatient mar and is never dispensed and administered.) no other system/software/device affects our patients safety more than the information system in use. I feel like i am walking through a field of land mines with this system. Cerner maintains that the system is functioning as designed. There is absolutely no safety net at all. When vendors provide it systems to hospitals/healthcare organizations, what agency approves these products and where is the oversight? can any company market and sell software for medication prescribing without oversight? where is the vetting process for these software applications? (b)(6).

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Brand Name CERNER
Type of Device CALCULATOR/DATA PROCESSING MODULE, FOR CLINICAL USE
Manufacturer *(Section D)* CERNER
MDR Report Key 6979199
Report Number MW5072962
Device Sequence Number 1
Product Code JQP[24]
Report Source Voluntary
***2* DeviceS WERE Involved in the Event:** 1 2
***0* PatientS WERE Involved in the Event:**
Date FDA Received 10/26/2017
Device Operator NO INFORMATION
Was Device Available For Evaluation? No Answer Provided
Was the Report Sent to FDA?
Event Location No Information
Was Device Evaluated By Manufacturer?

Is The Device Single Use?
Is this a Reprocessed and Reused Single-Use Device?
Type of Device Usage

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